Complete Summary

GUIDELINE TITLE

Guidelines for percutaneous coronary interventions.

BIBLIOGRAPHIC SOURCE(S)

Silber S, Albertsson P, Aviles FF, Camici PG, Colombo A, Hamm C, Jorgensen E, Marco J, Nordrehaug JE, Ruzyllo W, Urban P, Stone GW, Wijns W. Guidelines for percutaneous coronary interventions: the Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Eur Heart J 2005 Apr;26(8):804-47. [404 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Coronary artery disease (CAD) including:

- Acute coronary syndromes (ACS) without ST-segment elevation (unstable angina [UA] or non-ST-segment elevation myocardial infarction [NSTEMI])
- Acute coronary syndrome with ST-segment elevation (ST-segment elevation myocardial infarction [STEMI])

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation

Management
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To give practically oriented recommendations on when to perform percutaneous coronary intervention (PCI) on the basis of currently available published data derived from randomized and nonrandomized clinical studies

TARGET POPULATION

Patients with coronary artery disease (CAD)

INTERVENTIONS AND PRACTICES CONSIDERED

Percutaneous Coronary Intervention (PCI)

1. Primary PCI (within 12 hours of symptom onset)
2. Rescue PCI (when thrombolysis fails)
3. Emergency (multivessel) PCI (in cardiogenic shock)
4. Routine post-thrombolysis coronary angiography and PCI
5. Ischaemia-guided PCI after successful thrombolysis

Adjunctive Medications

1. Nitroglycerin (NTG)
2. Adenosine
3. Verapamil
4. Nitroprusside
5. Acetylsalicylic acid (ASA)
6. Ticlopidine and clopidogrel
7. Unfractionated heparin (UFH)
8. Low-molecular-weight heparins (LMWHs)
9. Glycoprotein (GP) IIb/IIIa inhibitors
10. Direct thrombin inhibitors

Adjunctive Devices for PCI

1. Intracoronary brachytherapy for in-stent restenosis
2. Cutting balloon

3. Rotablation
4. Directional coronary atherectomy
5. Embolic protection devices
6. Adjunctive diagnostic technology

Drug-Eluting Stents (DES)

1. Cypher stent (Sirolimus)
2. Taxus stent (Paclitaxel)

MAJOR OUTCOMES CONSIDERED

- Rates of procedural complications including death, myocardial infarction, stroke, and need for re-intervention
- Survival and event-free survival rates
- Success rates of percutaneous coronary intervention (PCI) as defined by procedural and clinical criteria (i.e., relief of signs and symptoms, rate of re-stenosis)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature review was performed using Medline (PubMed) for peer-reviewed published literature. The use of abstracts was avoided. According to the European Society of Cardiology (ESC) recommendations for task force creation and report production, clinical trials presented at a major cardiology meeting were included for decision-making on the condition that the authors provided a draft of the final document to be submitted for publication.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Data derived from multiple randomized clinical trials or meta-analyses
B. Data derived from a single randomized clinical trial or large non-randomized studies

C. Consensus of opinion of the experts and/or small studies, retrospective studies, registries

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus could be achieved for all recommendations on the basis of evidence. To verify the applicability of the recommendations to a specific area, the expert panel emphasized the importance of the primary endpoint for the randomized trials, giving high priority to the importance of significantly improving patients' outcome as the primary endpoint investigated in an adequately powered sample size.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classes of Recommendations

Class I: Evidence and/or general agreement that a given diagnostic procedure/treatment is beneficial, useful, and effective

Class II: Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the treatment

Class IIa: Weight of evidence/opinion is in favour of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (A-C) and classes of recommendations (I, II, IIa, and IIb) are defined at the end of the "Major Recommendations" field.

Indications for Percutaneous Coronary Interventions (PCI)

Indications for PCI in Stable Coronary Artery Disease (CAD)

Recommendations for PCI indications in stable CAD

Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Objective large ischaemia	I A	Parisi, Folland, & Hartigan, 1992[a]; Hartigan et al., 1998[a]; Pepine et al., 1994[b]
Chronic total occlusion (CTO)	IIa C	
High surgical risk, including left ventricular ejection fractions (LV-EF) <35%	IIa b	Morrison et al., 1999
Multi-vessel disease/diabetics	IIb C	
Unprotected left main (LM) stenosis in the absence of other revascularization options	IIb C	
Routine stenting of de novo lesions in native coronary arteries	I A	Serruys et al., 1994; Fischman et al., 1994
Routine stenting of de novo lesions in venous bypass grafts	I A	Savage et al., 1997; Hanekamp et al., 2003

Assuming that the lesions considered most significant are technically suited for dilation and stenting, the levels of recommendation refer to the use of stainless steel stents.

[a] The benefit was limited to symptom improvement and exercise capacity.

[b] The Asymptomatic Cardiac Ischemia Pilot (ACIP) study is not a pure trial of PCI vs. medical treatment as half of the revascularization patients were treated with bypass graft surgery. Drug-eluting stents are discussed subsequently.

Summary

PCI can be considered a valuable initial mode of revascularization in all patients with stable CAD and objective large ischaemia in the presence of almost every lesion subset, with only one exception: CTO that cannot be crossed. In early

studies, there was a small survival advantage with coronary artery bypass graft (CABG) surgery compared with PCI without stenting. The addition of stents and newer adjunctive medications improved the outcome for PCI. The decision to recommend PCI or CABG surgery will be guided by technical improvements in cardiology or surgery, local expertise, and patients' preference. However, until proved otherwise, PCI should be used only with reservation in diabetics with multi-vessel disease and in patients with unprotected LM stenosis. The use of drug-eluting stents might change this situation.

Indications for PCI in Acute Coronary Syndromes (ACSs) without ST-Segment Elevation

Characteristics of patients with NSTE-ACS at high acute, thrombotic risk for rapid progression to myocardial infarction or death that should undergo coronary angiography within 48 hours:

1. Recurrent resting pain
2. Dynamic ST-segment changes: ST- segment depression $\geq$0.1 mV or transient (<30 min) ST-segment elevation $\geq$0.1/ mV
3. Elevated Troponin-I, Troponin-T, or CK-MB levels
4. Haemodynamic instability within the observation period
5. Major arrhythmias (ventricular tachycardia, ventricular fibrillation)
6. Early post-infarction unstable angina
7. Diabetes mellitus

Recommendations of PCI indications in non-ST-segment elevation acute coronary syndrome (NSTE-ACS) (unstable angina [UA] or non ST-elevation myocardial infarction [NSTEMI])

Procedure	Indication	Classes of recommendation and levels of evidence	Randomized studies for levels A and B
Early PCI (<48h)	High-risk NSTE-ACS	I A	"Invasive compared with non-invasive," 1999; Cannon et al., 2001; Fox et al., 2002
Immediate PCI (<2.5 h)	High-risk NSTE-ACS	IIa B	Neumann et al., 2003
Routine stenting in de novo lesions	All NSTE-ACS	I C	

Summary

Patients presenting with NSTE-ACS (UA or NSTEMI) have to be first stratified for their risk of acute thrombotic complications. A clear benefit from early angiography (<48h) and, when needed, PCI or CABG surgery has been reported only in the high-risk groups. Deferral of intervention does not improve the outcome. Routine stenting is recommended on the basis of the predictability of the result and its immediate safety.

Indications for PCI in ACS with ST-Segment Elevation (STE-ACS)

Recommendations for PCI in STE-ACS (STEMI)

Procedure	Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A and B
Primary PCI	Patients presenting <12 hours after onset of chest pain/other symptoms and preferably up to 90 minutes after first qualified medical contact; PCI should be performed by an experienced team	I A	Grines et al., 1993; "A clinical trial," 1997; Aversano et al., 2002; Widimsky et al., 2000; Widimsky et al., 2003; Andersen et al., 2003
Primary stenting	Routine stenting during primary PCI	I A	Suryapranata et al., 1998; Grines et al., 1999; Stone et al., 2002
Primary PCI	When thrombolysis is contraindicated	I C	
Primary PCI	Preferred more than thrombolysis for patients presenting within >3 hours and <12 hours after onset of chest pain/other symptoms	I C	
Rescue PCI	If thrombolysis failed within 45-60 minutes after starting the administration	I B	Gershlick et al., 2005
Emergency (multi-vessel) PCI	Cardiogenic shock in association with an intra-aortic balloon pump (IABP) even >12 hours to <36 hours	I C	
Routine post-thrombolysis coronary angiography and PCI, if applicable	Up to 24 hours after thrombolysis, independent of angina and/or ischaemia	I A	Scheller et al., 2003; Fernandez-Aviles et al., 2004; Le May et al., 2005
Ischaemia-guided PCI after successful thrombolysis	Pre-discharge angina and/or ischaemia after (first) STEMI treated with thrombolysis	I B	Madsen, 1997

Summary

Primary PCI should be the treatment of choice in patients presenting with STEMI in a hospital with PCI facility and an experienced team. Patients with contraindications to thrombolysis should be immediately transferred for primary PCI, because this might be their only chance for quickly opening the coronary artery. In cardiogenic shock, emergency PCI for complete revascularization may be life-saving and should be considered at an early stage. Compared with thrombolysis, randomized trials that transferred the patients for primary PCI to a "heart attack centre" observed a better clinical outcome, despite transport times leading to a significantly longer delay between randomization and start of the treatment. The superiority of primary PCI over thrombolysis seems to be especially clinically relevant for the time interval between 3 and 12 hours after onset of chest pain or other symptoms on the basis of its superior preservation of myocardium. Furthermore, with increasing time to presentation, major adverse cardiac event (MACE) rates increase after thrombolysis, but appear to remain relatively stable after primary PCI.

Within the first 3 hours after onset of chest pain or other symptoms, both reperfusion strategies seem equally effective in reducing infarct size and mortality. Therefore, thrombolysis is still a viable alternative to primary PCI, if it can be delivered within 3 hours after onset of chest pain or other symptoms. Primary PCI compared with thrombolysis significantly reduced stroke. Overall, we prefer primary PCI over thrombolysis in the first 3 hours of chest pain to prevent stoke and, in patients presenting 3-12 hours after the onset of chest pain, to salvage myocardium and also prevent stroke. At the moment, there is no evidence to recommend facilitated PCI.

Rescue PCI is recommended if thrombolysis failed within 45 to 60 minutes after starting the administration. After successful thrombolysis, the use of routine coronary angiography within 24 hours and PCI, if applicable, is recommended even in asymptomatic patients without demonstrable ischaemia to improve outcomes. If a PCI centre is not available within 24 hours, patients who have received successful thrombolysis with evidence of spontaneous or inducible ischaemia before discharge should be referred to coronary angiography and revascularized accordingly--independent of maximal medical therapy.

Adjunctive Medications for PCI

A routine pre-treatment with an intracoronary bolus of nitroglycerin (NTG) is recommended to unmask vasospasm, to assess the true vessel size, and to reduce the risk of vasospastic reactions during the procedure (Recommendation for NTG: I C). The bolus may be repeated during and at the end of the procedure, depending on the blood pressure. In the rare case of spasm resistant to NTG, verapamil is a useful alternative.

In the setting of "no/slow reflow" (see section 4.5, "Embolic protection devices," in the original guideline document), many reports investigated the intracoronary application of verapamil and adenosine in various dosages. The direct nitric oxide donor nitroprusside (NPN) seems also to be effective and safe treatment of reduced blood flow or no-reflow associated with PCI. In addition, an intra-aortic balloon pump (IABP) might be helpful. The combination of adenosine and nitroprusside provided an improvement in coronary flow that was better than the

improvement with intracoronary adenosine alone. (Recommendations for adenosine, verapamil, and NPN for no/slow reflow: IIa C).

Acetylsalicylic Acid (ASA)

ASA in Stable CAD

ASA continues to play an important role in reducing ischaemic complications related to PCI. If patients are not chronically pre-treated or when there is doubt about medication compliance, a loading dose of 500 mg orally should be given more than 3 hours prior or at least 300 mg intravenously directly prior to the procedure. Only in patients with known allergy against ASA should it be omitted. As pointed out in the European Society of Cardiology consensus document, for chronic use, there is no need for doses higher than 100 mg daily. (Recommendation for ASA in PCI for stable CAD: I B).

ASA in NSTE-ACS

ASA is universally recommended as standard therapy in NSTE-ACS with and without PCI. (Recommendation for ASA in PCI for NSTE-ACS: I C).

ASA in STE-ACS (STEMI)

Despite the limitations and side effects of ASA, it should be given to all patients with STEMI (if clinically justifiable) as soon as possible after the diagnosis is established. (Recommendation for ASA in PCI for STEMI: I B).

Ticlopidine and Clopidogrel

Ticlopidine and clopidogrel are potent antiplatelet compounds. According to three randomized, controlled studies and several registries and meta-analyses, clopidogrel seems to be at least as effective as ticlopidine. Compared with ticlopidine, clopidogrel has fewer side-effects and is better tolerated.

Recommendations for clopidogrel as adjunctive medication for PCI

Indication	Initiation and duration	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Pre-treatment of planned PCI in stable CAD	Loading dose of 300 mg at least 6 hours before PCI, ideally the day before	I C	
Pre-treatment for primary PCI: • In STEMI or immediate	Loading dose of 600 mg, immediately after first medical contact, if clinically justifiable	I C	

Indication	Initiation and duration	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
PCI • In NSTE-ACS or ad hoc PCI • In stable CAD			
After all bare metal stent procedures	3 to 4 weeks	I A	Bertrand et al., 2000; Taniuchi, Kurz, & Lasala, 2001; Müller et al., 2000
After vascular brachytherapy	12 months	I C	
After drug-eluting stents	6 to 12 months	I C	
After NSTE-ACS	Prolonged for 9 to 12 months	I B	Yusuf et al., 2001

Summary

The "double" antiplatelet therapy with ASA and clopidogrel is standard for the pre-treatment of patients with stable CAD undergoing PCI--with or without planned stent implantation. After implantation of a bare metal stent, clopidogrel must be continued for 3 to 4 weeks and ASA lifelong. In patients presenting with NSTE-ACS, ASA and, if clinically justifiable, immediate administration of clopidogrel, is the basic standard antiplatelet regimen. After the acute phase, the continuation of 100 mg/day ASA + clopidogrel 75 mg/day over 9 to 12 months is beneficial. ASA should be given intravenously to all patients with STEMI as soon as possible after the diagnosis is established, if clinically justifiable. With the concept of primary PCI and primary-stenting in STEMI, clopidogrel will be additionally administered in these patients. After brachytherapy, clopidogrel should be administered in addition to ASA for 12 months and after drug-eluting stents for 6 to 12 months to avoid late vessel thrombosis.

Unfractionated Heparin (UFH)

UFH for PCI in stable CAD

UFH is given as an intravenous bolus either under activated clotting time (ACT) guidance or in a weight-adjusted manner. Because of marked variability in UFH bio-availability, ACT- guided dosing is advocated, especially for prolonged procedures when additional bolus (-es) may be required. The therapeutic response to UFH in general is difficult to predict. There is evidence that its benefit is linked to an effective dose, although low doses (5000 IU or lower) have been used in routine procedures. Continued heparinization after completion of the

procedure, either preceding or following arterial sheath removal is not recommended.

UFH for PCI in NSTE-ACS

Adding UFH as a standard regimen is usually recommended on the basis of a meta-analysis of six smaller randomized trials showing a 7.9% rate of death/myocardial infarction in patients with unstable angina treated with ASA plus heparin compared with 10.3% in those treated with ASA alone. Discontinuation of UFH in patients with unstable angina carries the inherent risk of a rebound effect.

UFH for PCI in STE-ACS (STEMI)

UFH is the standard therapy in patients with STEMI especially for those undergoing primary PCI. (Recommendation for unfractionated heparin for all PCI procedures: I C)

Low-Molecular Weight Heparins (LMWHs)

LMWHs for PCI in stable CAD

The data on LMWHs as sole anticoagulant during PCI in stable CAD patients are limited. To be on the safe side, it is suggested that UFH should be added in patients arriving on pre-treatment with LMWHs, according to the interval of the last LMWH dose.

LMWHs for PCI in NSTE-ACS

Switching from UFH to LMWH and vice versa should generally be avoided. If LMWH has been administered prior to PCI, the administration of additional anticoagulant therapy depends on the timing of the last dose of LMWH.

Combining the results of several studies, UFH should be preferred in high-risk NSTE-ACS patients with planned invasive strategy. Furthermore, although enoxaparin can be administered before PCI in NSTE-ACS, the Task Force recommends UFH because of its easier reversibility by the administration of protamine. There is no firm evidence that enoxaparin can be used safely in the cathlab, but this possibility is currently being explored.

If an invasive strategy is, for some reason, not applicable in a high-risk NSTE-ACS patient, enoxaparin could be preferred for reducing ischaemic complications. (Recommendation for LMWHs as a replacement for UFH in high-risk NSTE-ACS, if invasive strategy is not applicable: I C)

LMWHs for PCI in STE-ACS (STEMI)

Unless more data from pivotal studies are provided, there is no evidence to support the preference of LMWHs over UFH for PCI in STEMI.

Summary

UFH is given as an intravenous bolus under activated clotting time (ACT) guidance. Because of their pharmacologic advantages, LMWHs are considered to be more predictable anticoagulants, not requiring laboratory monitoring. However, the data on LMWHs as sole anticoagulant during PCI in stable CAD patients is limited. UFH is to be preferred in high-risk NSTE-ACS patients with planned invasive strategy and in lower risk patients with planned conservative strategy. If in high-risk NSTE-ACS patients, an invasive strategy is not applicable for some reason, enoxaparin may be preferred, taking into account an increase in minor bleeding. In patients with STEMI undergoing primary PCI, UFH is the standard therapy.

Glycoprotein IIb/IIIa Inhibitors

See table below under "Direct Thrombin Inhibitors."

Direct Thrombin Inhibitors

The table below contains recommendations pertaining to both glycoprotein inhibitors and direct thrombin inhibitors.

Recommendations for glycoprotein (GP) IIb/IIIa inhibitors and bivalirudin as adjunctive medications for PCI

Medication	Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Abciximab, eptifibatide, tirofiban, in stable CAD	Complex lesions, threatening/actual vessel closure, visible thrombus, no/slow reflow	IIa C	
Abciximab, eptifibatide in NSTE-ACS	Immediately before PCI in high-risk patients	I C	
Tirofiban, eptifibatide in NSTE-ACS	Pre-treatment before diagnostic angiography and possible PCI within 48 hours in high-risk patients (upstream)	I C	
Abciximab in NSTE-ACS	In high risk patients with known coronary anatomy in the 24 hours before planned PCI	I C	
Abciximab in STEMI	All primary PCI (preferably in high-risk patients)	IIa A	Montalescot et al., 2001; Antoniucci et al., 2003
Bivalirudin	Replacements for UFH or LMWHs (± GP IIb/IIIa inhibitors) to reduce bleeding complications	IIa C	

Medication	Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Bivalirudin	Replacement for UFH in heparin-induced thrombocytopenia (HIT)	I C	

Summary

Given the overall low risk of PCI in stable CAD patients, the potential of GP IIb/IIIa inhibitors to increase the risk of bleeding complications, and the considerable cost of their use, they are not a part of standard periprocedural medication. The use of GP IIb/IIIa inhibitors for PCI in stable angina should be considered on an elective basis: whenever there is a higher than average risk of acute thrombotic complications in stable CAD (complex interventions, unstable lesions, as bail-out medication in case of threatening/actual vessel closure, visible thrombus, or no/slow-reflow phenomenon), GP IIb/IIIa inhibitors are helpful.

In NSTE-ACS, GP IIb/IIIa inhibitors should be added only in high-risk patients, in whom an invasive strategy is planned. For "upstream" management (i.e., initiating therapy when the patient first presents to the hospital and catheterization is not planned or available within 2.5 hours), tirofiban and eptifibatide show benefit. If cardiac catheterization is likely to be performed within 2.5 hours, GP IIb/IIIa inhibitors could possibly be postponed and abciximab or eptifibatide initiated in the catheterization laboratory. If, for some reason, the delay between diagnostic catheterization and planned PCI is up to 24 hours, abciximab can also be administered.

In patients with STEMI, the GP IIb/IIIa inhibitors tirofiban and eptifibatide are less well investigated. In STEMI, stenting plus abciximab seems to be a more evidence-based reperfusion strategy. Bivalirudin is suggested today as a replacement for UFH (or LMWHs) because of significantly less bleeding compared with UFH alone or UFH + GP IIb/IIIa inhibitors. Bivalirudin is unanimously recommended for PCI as a replacement for UFH (and LMWHs) in patients with HIT.

Adjunctive Devices for PCI

Recommendations for adjunctive PCI devices

Device	Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Brachytherapy	In-stent restenosis in native coronary arteries	I A	Teirstein et al., 1999; Leon et al., 2001; Waksman et al., 2000 & 2003; Popma et al., 2002; Waksman et

Device	Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
			al., "Use of localized intracoronary beta radiation," 2002
Brachytherapy	In-stent restenosis in saphenous bypass grafts	I B	Waksman et al., "Intravascular gamma radiation," 2002
Cutting balloon	In-stent restenosis in conjunction with brachytherapy to avoid geographical miss, slippage of balloons with risk of jeopardizing adjacent segments	IIa C	
Rotablation	Fibrotic or heavily calcified lesions that cannot be crossed by a balloon or adequately dilated before planned stenting	I C	
Directional coronary atherectomy (DCA)	De nova ostial or bifurcational lesions in experienced hands	IIb C	
Distal embolic protection	Saphenous vein grafts	I A	Baim et al., 2002; Stone et al., 2003
Distal and proximal protection devices	ACS with high thrombus load in native coronary arteries	IIb C	
Polytetrafluoroethylene (PTFE)-covered stents	Emergency tool for coronary perforations	I C	

Summary

Intracoronary brachytherapy proved to be the only evidence-based non-surgical treatment of in-stent restenosis. To avoid late vessel thrombosis, a prolonged intake of clopidogrel for 1 year after radiation therapy is necessary.

Rotablation is recommended for fibrotic or heavily calcified lesions that can be wired but not crossed by a balloon or adequately dilated before planned stenting. One must know how to manage the complications inherent to rotablation.

PCI of saphenous vein grafts (SVGs) or primary PCI in ACS with a high thrombotic load is at elevated risk for coronary embolization. Two distal protection devices (GuardWire and FilterWire EX) have proved their safety and efficacy as an adjunctive device for PCI of SVG lesions.

Whether balloon occlusion and aspiration systems of filter-based catheters will be preferred in other clinical settings such as primary PCI for STEMI will require more randomized trials with a clinical primary endpoint. At present, no definite recommendations can be given regarding the use of embolic protection devices in the setting of STEMI.

Adjunctive Diagnostic Technology

Refer to the original guideline document for the discussion on adjunctive diagnostic technology including intravascular ultrasound (IVUS) and fractional flow reserve.

Drug-Eluting Stents (DES)

Indications for DES

Recommendations for the use of DES in de novo lesions of native coronary arteries

DES	Indication	Classes of recommendations and levels of evidence	Randomization studies for levels A and B
Cypher stent	De novo lesions in native vessels according to the inclusion criteria	I B	Moses et al., 2003
Taxus stent	De novo lesions in native vessels according to the inclusion criteria	I B	Stone et al., 2004
Taxus stent	De novo long lesions in native vessels according to the inclusion criteria	I B	Dawkins et al., 2005

There are only three positive controlled, randomized, adequately powered trials with a primary clinical endpoint at an appropriate time interval. Main clinical inclusions criteria for SIRIUS, TAXUS-IV, and TAXUS-VI were similar: stable or unstable angina or documented ischaemia. The stenoses had to be in native vessels >50 <100%. In SIRIUS, reference diameter and lesion length for inclusion were 2.5 to 3.5 mm and 15 to 30 mm, respectively. The reference diameter in TAXUS-IV and TAXUS-VI was 2.5 to 3.75 mm. In TAXUS-IV, the lesion length was 10 to 28 mm and in TAXUS-VI 18 to 40 mm. The main common exclusion criteria were acute MI or status post MI with elevated creatine kinase (CK)/creatine kinase-MB (CK-MB), bifurcational or ostial lesions, unprotected left main, visible thrombus, severe tortuosity, and/or calcification.

Summary

Only two DES have shown significantly positively effects in prospective, randomized studies with clinical primary endpoints at an appropriate time: the Cypher stent (Sirolimus) and the Taxus stent (Paclitaxel). Evidence-based

recommendations for the use of DES must focus on the enrollment criteria of SIRIUS, TAXUS-IV, and TAXUS-VI. In these patients, target vessel revascularization (TVR) rates were single-digit numbers. Subgroup analyses regarding smaller vessels and patients with diabetes are encouraging. Although registry data for in-stent restenosis as well as for other lesions with high risk for in-stent restenosis (bifurcational or ostial lesions, chronic total occlusions, multi-vessel disease, bypass stenosis, and unprotected left main stenoses) is promising, randomized trials must be conducted for achieving higher levels of evidence in these special subsets of patients. At present, we consider the prolonged (at least 6 months) administration of clopidogrel (in addition to ASA) as mandatory to avoid late stent thrombosis. Therefore, in patients undergoing or who soon will be undergoing urgent major extracardiac surgery, DES should not be implanted. In these patients, bare stents are probably the safer choice. Physicians and patients must be made aware that clopidogrel should not be discontinued too early, even for minor procedures like dental care.

Definitions:

Levels of Evidence

A. Data derived from multiple randomized clinical trials or meta-analyses
B. Data derived from a single randomized clinical trial or large non-randomized studies
C. Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Classes of Recommendations

Class I: Evidence and/or general agreement that a given diagnostic procedure/treatment is beneficial, useful, and effective

Class II: Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the treatment

Class IIa: Weight of evidence/opinion is in favour of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for the management of:

- Patients presenting with non-ST-elevation acute coronary syndrome (NSTE-ACS)
- Patients with ST-segment elevation myocardial infarction (STEMI) who present within 12 hours after the onset of symptoms

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of percutaneous coronary intervention (PCI) in the treatment of patients with coronary artery disease (CAD)

POTENTIAL HARMS

- Ischaemic complications of percutaneous coronary intervention (PCI)
- Adverse effects of adjunctive medications for PCI (i.e., bleeding associated with glycoprotein IIb/IIIa inhibitors, unfractionated heparin, low-molecular-weight heparins, and bivalirudin)

CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute contraindications to thrombolysis are the following conditions: aortic dissection, status post haemorrhagic stroke, recent major trauma/surgery, gastrointestinal (GI) bleeding within the last month or a known bleeding disorder.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads
Pocket Guide/Reference Cards
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Silber S, Albertsson P, Aviles FF, Camici PG, Colombo A, Hamm C, Jorgensen E, Marco J, Nordrehaug JE, Ruzyllo W, Urban P, Stone GW, Wijns W. Guidelines for percutaneous coronary interventions: the Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Eur Heart J 2005 Apr;26(8):804-47. [404 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Apr

GUIDELINE DEVELOPER(S)

European Society of Cardiology - Medical Specialty Society

SOURCE(S) OF FUNDING

European Society of Cardiology

GUIDELINE COMMITTEE

Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The chosen experts in these writing panels are asked to provide disclosure statements of all relationships they may have which might be perceived as real or potential conflicts of interest. These disclosure forms are kept on file at the European Heart House, headquarters of the European Society of Cardiology (ESC).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the European Society of Cardiology (ESC) Web site.

Print copies: Available from Elsevier Science Ltd. European Heart Journal, ESC Guidelines - Reprints, 32 Jamestown Road, London, NW1 7BY, United Kingdom. Tel: +44.207.424.4422; Fax: +44 207 424 4515; Web site: http://www.eurheartj.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Percutaneous coronary interventions. Pocket guidelines. Sophia Antipolis (France): European Society of Cardiology, 2005. Electronic copies: An order form for ESC pocket guidelines is available in Portable Document Format (PDF) from the European Society of Cardiology (ESC) Web site. Also available for PDA download from the ESC Web site.
- Guidelines for percutaneous coronary interventions: The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Educational slides. Sophia Antipolis (France): European Society of Cardiology, 2005. Electronic copies: Available in Microsoft PowerPoint from the European Society of Cardiology (ESC) Web site.

PATIENT RESOURCES

None available

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